

REMARKS

IDS

A corrected information disclosure is filed herewith.

Specification

A brief description of the drawings is inserted into the specification.

Priority

Applicants respectfully disagree with the allegations that the previous priority application does not support the claimed limitations of the instant application. The priority application PCT/EP99/05239 provides both a written description and enablement for all the claims in this application, both before and after the current amendments.

The Office Action does not indicate which claims allegedly lack the benefit of priority to the priority application, but recites in the allegations limitations appearing in claim 2 only, which along with its dependent claims was cancelled from this application without prejudice or disclaimer.

Because it is not clear whether claim 3 and its dependent claims were included in the allegation that the priority document does not provide for priority, applicants provide the following comments.

Claim 3 recites, a method of protecting the skin of a human patient from exogenous high surfactant concentration (element 1), comprising administering, to a patient whose skin is in need of protection from high surfactant concentration, a composition comprising at least one compound of the formulae Ia or Ib, e.g., recited as ectoin hereinafter (element 2), wherein the composition does not contain said exogenous surfactant (element 3), and wherein said exogenous surfactant is not sodium dodecyl sulfate (element 4).

In PCT/EP99/05239 (all page and line numbers regarding priority will refer to a location in this PCT application) elements 1 and 2 have support on page 13, lines 8-18, especially lines 15-18, where it is recited that “

Ectoin-containing formulations can, for example, protect the skin barrier against the harmful effect of sodium dodecyl sulfate (SDS). The use of a cosmetic ectoin-containing emulsion can significantly reduce the transepidermal water loss e.g. by up to 40% (FIG. 1) Skin pretreated with an ectoin-containing cosmetic formulation is insensitive toward damage of the skin barrier by the surfactant (SDS). As a result of the use of an

ectoin-containing emulsion, the skin is better protected against surfactant damage of the skin and the water loss associated therewith.
(Emphasis added.)

Element 3 has support in the same material recited above. One of ordinary skill in the art would understand the disclosure to refer to protecting from a surfactant's effects by the use of the ectoin-containing composition which does not contain that surfactant within the composition itself. If the ectoin-containing composition would contain the surfactant from which protection is sought, the composition would, illogically and unreasonably, both contribute to the problem and solve it at the same time. One of ordinary skill in the art would understand from the disclosure that such is not what the disclosure teaches, i.e., to exacerbate a problem and solve it, but rather teaches the protection from a surfactant that is exogenous to the composition containing the ectoin.

See MPEP 2173.05, Negative Limitations, summarizing the law and the USPTO's position on support for a negative limitation stating that

a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a prima facie case for lack of descriptive support. *Ex parte Parks*, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993).

Element 4 has support on page 13, lines 8-10, where it is recited that "ectoin-containing formulations can, for example, protect the skin barrier against the harmful effect of sodium dodecyl sulfate." See once again MPEP 2173.05, Negative Limitations, stating that

if alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984).

Applicants explicitly recite that the surfactant can be sodium dodecyl sulfate, thus thereby providing support for excluding said sodium dodecyl sulfate.

Reconsideration is respectfully requested.

Duplicate Claims

This issue is moot in view of the cancellations of claims.

Claim Rejections Under 35 USC 102

This rejection is moot in view of the priority to PCT/EP99/05239. The date of the reference in question is August 2000, which is after the filing date of the PCT priority application in which support for the claimed invention is present.

Claim Rejections Under 35 USC 103

Applicants respectfully disagree with the rejection. Just because detergents were disclosed in the art to cause dry skin, one of ordinary skill in the art would not have been motivated to take a method of the claims of US '071, e.g., a dominating generic method for treating a patient suffering from aged, dry or irritated skin or of dry, flaky scalp or increasing or stabilizing the moisture content of a patient's skin to achieve the particular claimed invention herein, the protection of the skin from exogenous high surfactant concentration. Nothing in the references teaches or suggests the administration of ectoine or ectoine derivatives as defined in the claims to skin in need of protection from high surfactant concentration, nor would one of ordinary skill in the art expect that such administration would provide such benefit to the skin.

Even though not necessary for establishing the patentability of the claimed invention, applicants point to Example 6 in the specification which demonstrates that the compounds of the invention treat and protect cells that have been exposed to various exogenous surfactants at high concentrations by demonstrating that the cell membrane is stabilized from stress caused by the various exogenous surfactants. The test is described in more detail on page 12 of the specification. The results are provided in figures 5-9, which demonstrate a dose response relationship for ectoin as also discussed in example 6. One of ordinary skill in the art would not have expected these results based on the disclosure of the prior art.

Reconsideration is respectfully requested.

Obviousness-Type Double Patenting

The arguments with regard to obviousness from above are incorporated herein.

Nothing in these references teaches or renders obvious the claimed invention for the reasons discussed above. Thus, for the same reasons at least as the claims are not obvious, there is also no obviousness-type double patenting.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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